Complete Summary

GUIDELINE TITLE

The use of hormonal contraception in women with coexisting medical conditions.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). The use of hormonal contraception in women with coexisting medical conditions. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Jul. 14 p. (ACOG practice bulletin; no. 18). [92 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling

Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide information to facilitate contraceptive counseling and selection for women with coexisting medical conditions

TARGET POPULATION

Women who have one or more of the following coexisting medical conditions or risk factors:

- Older than 35 years
- Smoke tobacco products
- Hypertension
- Diabetes
- Migraine headaches
- Fibrocystic breast changes, fibroadenoma, or family history of breast cancer
- Uterine fibroids
- Lipid disorders
- Breastfeeding/postpartum
- Take concomitant medication
- Anticipate surgery
- Venous thromboembolism (VTE)
- Systemic lupus erythematosus (SLE)
- Sickle cell disease

INTERVENTIONS AND PRACTICES CONSIDERED

1. Combination oral contraceptives (OCs)
2. Other forms of contraception, including progestin-only oral contraceptives, depot medroxyprogesterone acetate (DMPA), or implants, for women with contraindications to combination oral contraceptives

MAJOR OUTCOMES CONSIDERED

- Effectiveness of contraception
- Patient morbidity

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources were used to conduct a literature search to locate relevant articles published between January 1985 and March 1998. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final

guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

The following recommendations are based on good and consistent scientific evidence (Level A):

- Women with fibroadenoma, benign breast disease with epithelial hyperplasia with or without atypia, or a family history of breast cancer are at little or no additional risk of breast cancer because of oral contraceptive (OC) use. Therefore, OCs can be prescribed for such women if they are otherwise appropriate candidates.
- Progestin-only preparations are safe and preferable forms of hormonal contraception for lactating women. Combination OCs are not recommended as the first choice for breastfeeding mothers because of the negative impact of contraceptive doses of estrogen on lactation. However, use of combination OCs by well-nourished breastfeeding women does not appear to result in infant development problems; therefore, their use can be considered once milk flow is well established.
- Hormonal contraceptive effectiveness is compromised by the use of the antibiotics rifampin and griseofulvin; thus, women taking these antibiotics should use nonhormonal contraceptives.
- Progestin-only preparations are appropriate for women at increased risk for venous thromboembolism (VTE). Combination OCs are not recommended for women with a documented history of unexplained VTE or VTE associated with pregnancy or exogenous estrogen use, unless they are taking anticoagulants.
- Combination OCs should be prescribed with caution, if ever, to women who are older than 35 years and are smokers. Women younger than 30 years who smoke and are otherwise healthy generally can be prescribed combination OCs.
- If desired, healthy, nonsmoking women doing well on combination OCs may continue their use until menopause.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Women with well-controlled and monitored hypertension aged 35 years and younger are appropriate candidates for a trial of combination OCs formulated with 35 micrograms or less of estrogen, provided they are otherwise healthy with no evidence of end-organ vascular disease and do not smoke cigarettes. If blood pressure remains well controlled several months after initiating OCs, use can be continued.
- The use of combination OCs by women with diabetes should be limited to such women who do not smoke, are younger than 35 years, and are

otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular disease.

- Women with migraine headaches who have focal neurologic signs are not appropriate candidates for OC use. Combination OCs can be used by women with simple migraine headaches (i.e., no focal neurologic signs) if they do not smoke, are younger than 35 years, and are otherwise healthy. If such women experience increased frequency or severity of headaches or develop headaches with focal neurologic signs or symptoms, they should discontinue OC use.
- Combination OCs may be beneficial in treating dysmenorrhea and menorrhagia in women with uterine fibroids.
- The risks associated with stopping OCs 1 month or more before major surgery should be balanced against the risks of an unintended pregnancy. In current OC users undergoing major surgical procedures, heparin prophylaxis should be considered. Because of the low perioperative risk of VTE, it generally is considered unnecessary to discontinue combination OCs before laparoscopic tubal sterilization or other brief surgical procedures.
- Progestin-only OCs and contraceptive injections appear to be the hormonal contraception methods of choice for women with systemic lupus erythematosus (SLE). Use of combination OCs in women with SLE can be considered if the women have stable or inactive disease and no history of thrombosis, nephropathy, or antiphospholipid antibodies.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Most women with controlled dyslipidemia can use combination OCs formulated with 35 micrograms or less of estrogen. In women with uncontrolled low-density lipoprotein (LDL) cholesterol greater than 160 mg/dL, a triglyceride level greater than 250 mg/dL, or multiple additional risk factors for coronary artery disease, alternative contraceptives should be considered.
- Depot medroxyprogesterone acetate (DMPA) has noncontraceptive benefits and is the contraceptive method of choice for many women with sickle cell disease.
- Progestin-only contraceptives may be appropriate for women with coronary artery disease, congestive heart failure, or cerebrovascular disease. However, combination oral contraceptives are contraindicated in these women.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of hormonal contraception in women with coexisting medical conditions

Benefits for Specific Populations

- Perimenopausal women benefit from the more regular menses and positive effect on bone mineral density (BMD) offered by combination oral contraceptives (OCs). In addition, use of combination OCs may reduce vasomotor symptoms in perimenopausal women.
- The reduced risk of endometrial and ovarian cancers associated with OC use is of particular importance to older women of reproductive age.
- Several large epidemiologic studies have observed that OC use does not induce the growth of uterine fibroids and may decrease bleeding disorders in women with menorrhagia or dysmenorrhea associated with uterine leiomyomata.
- The estrogen component of combination OCs enhances removal of low-density lipoprotein (LDL) and increases levels of high-density lipoprotein

(HDL) cholesterol, which can have a favorable effect on a woman's risk for coronary artery disease.
- Two controlled studies assessing the use of depot medroxyprogesterone acetate (DMPA) in women with sickle cell disease found that the use of DMPA reduced the incidence of painful crises.

POTENTIAL HARMS

Please refer to the original guideline document for a detailed discussion of the risks of oral contraception for women with specific coexisting conditions.

CONTRAINDICATIONS

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In women with the following conditions, use of progestin-only oral contraceptives, depot medroxyprogesterone acetate,* or implants may be safer than combination oral contraceptives. An intrauterine device also represents an appropriate contraceptive choice for women with these conditions.

- Migraine headaches
- Older than 35 years and smoke cigarettes
- History of thromboembolic disease
- Coronary artery disease
- Congestive heart failure
- Cerebrovascular disease
- Less than 2 weeks postpartum**
- Hypertension with vascular disease or older than 35 years
- Diabetes with vascular disease or older than 35 years
- Systemic lupus erythematosus with vascular disease, nephritis, or antiphospholipid antibodies
- Hypertriglyceridemia

*Because of its long duration of action and potential for hypoestrogenic effects, depot medroxyprogesterone acetate may be less appropriate than other progestin-only contraceptives for some women with these listed conditions.

**Use of an intrauterine devise may not be an appropriate contraceptive choice.

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jul (reviewed 2005)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004.

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